UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

IN RE CTI BIOPHARMA CORP. SECURITIES LITIGATION	Case No. 2:16-cv-00216-RSL Hon. Robert S. Lasnik Class Action ORAL ARGUMENT REQUESTED NOTE ON MOTION CALENDAR: March 10, 2017

MOTION TO DISMISS BY DEFENDANTS CTI BIOPHARMA CORP., JAMES A. BIANCO, LOUIS A. BIANCO, JACK W. SINGER, FREDERICK W. TELLING, REED V. TUCKSON, PHILLIP M. NUDELMAN, JOHN H. BAUER, KAREN IGNAGNI, RICHARD L. LOVE, AND MARY O. MUNDINGER

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PRELIMINARY STATEMENT[1]

Lead Plaintiffs seek to hold CTI, Bianco, and the Section 11 Individual Defendants liable for losses arising out of the United States FDA's February 2016 decision to temporarily place on hold clinical trials for pacritinib, one of CTI's pipeline cancer-treatment therapies. But the risks associated with pharmaceutical-industry investments are widely known, and chief among them is the risk that a regulatory agency will delay or reject a new-drug application. No defendant made *any* statement about the likelihood of pacritinib's regulatory approval. To the contrary, CTI disclosed to its investors repeatedly the risk that the FDA would not approve pacritinib for commercialization. The Court should reject Lead Plaintiffs' attempt to avoid the consequences of the risk that they assumed with eyes wide open—i.e., the risk that they would lose money if the relatively small biopharmaceutical company in which they invested failed within a particular time frame to commercialize one of its pipeline drugs—by manufacturing in hindsight a securities-fraud claim.

In early 2015, two Phase III CTI-sponsored pacritinib clinical trials were underway, PERSIST-1 and PERSIST-2, and CTI had engaged an Independent Data Monitoring Committee ("IDMC") to consult on clinical-trial mechanics and results. An IDMC is a panel of scientists with relevant expertise, but no regulatory authority. In fact, FDA and European Medicines Agency ("EMA") guidelines instruct that IDMC recommendations are purely advisory, and clinical-trial sponsors are in no way bound to accept them. The pacritinib IDMC recommended preliminarily in February 2015 that CTI stop permitting patients in PERSIST-1 who had received the best-available therapy ("BAT") during the first 24 weeks of treatment from subsequently "crossing over" to receive pacritinib. In so recommending, the IDMC highlighted non-

[1] This brief refers to (i) defendant CTI BioPharma Corp. as "CTI"; (ii) defendant James A. Bianco as "Bianco"; (iii) defendants James A. Bianco, Louis A. Bianco, Jack W. Singer, Frederick W. Telling, Reed V. Tuckson, Phillip M. Nudelman, John H. Bauer, Karen Ignagni, Richard L. Love, and Mary O. Mundinger as the "Section 11 Individual Defendants"; (iv) DAFNA LifeScience, LP, DAFNA LifeScience Select, LP, and Michael Li as the "Lead Plaintiffs"; (v) the November 8, 2016 Consolidated Class Action Complaint as the "CAC"; and (vi) the accompanying declaration of Leah Godesky, Esq. as the "Godesky Decl." Unless otherwise indicated, all emphasis is added and all citations and quotations are omitted.

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statistically significant post-24-week mortality and adverse-event data. The other independent statisticians and clinicians that CTI thereafter engaged to further analyze the data, however, unanimously rejected the IDMC's conclusion. CTI thus decided to continue the clinical trials without modification, while cautioning investors about a number of risks and uncertainties, including the IDMC's "crossover"-related concerns and the possibility that the FDA would not approve CTI's New Drug Application ("NDA"). In February 2016, the risk of which CTI had repeatedly warned its investors materialized when the FDA placed clinical trials on hold, citing concerns relating to "crossover" patients and preliminary PERSIST-2 data.

All five causes of action alleged in the CAC should be dismissed based on Lead Plaintiffs' failure to identify a single material false or misleading pacritinib-related statement by the Defendants. The CAC states no facts demonstrating the falsity of the alleged statements regarding pacritinib's gastrointestinal side effects, control of disease-related symptoms, clinical-trial top-line results, or Phase II clinical-trial results. Nor does the CAC identify a statement that was rendered misleading by the alleged failure to disclose an imbalance in mortality and adverse-event data between pacritinib and BAT-treated patients. And publicly available documents refute Lead Plaintiffs' claim that CTI's decision to discharge the original pacritinib IDMC was concealed.

Moreover, feedback and recommendations by the IDMC are immaterial under federal securities laws. Indeed, courts around the country have long declined to deem material nonbinding feedback and recommendations by industry *regulators*; imposing disclosure obligations on pharmaceutical companies with regard to statements by IDMCs—which have no regulatory authority at all—would be a significant departure from longstanding disclosure requirements. In addition to unreasonably burdening pharmaceutical companies with a never-ending reel of disclosures, it would confuse and mislead investors with disclosure of nonbinding and inconclusive findings.

CTI's securities-fraud claims (Counts III-IV) fail for at least three additional reasons.

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- **The CAC fails to plead scienter by CTI or Bianco.** The Private Securities Litigation Reform Act ("PSLRA") instructs that a securities-fraud claim must be dismissed, unless the complaint raises a "*strong inference* that the statements were intentionally false, misleading, or made with deliberate recklessness." *Ronconi v. Larkin*, 253 F.3d 423, 432 (9th Cir. 2001). The CAC fails to plead CTI's or Bianco's scienter because (among other reasons) the CAC alleges no facts demonstrating that CTI or Bianco *actually believed* that the FDA would reject pacritinib based on PERSIST-1 mortality and adverse-event data. To the contrary, CTI and Bianco adamantly and reasonably believed that the PERSIST-1 data would favorably support the pacritinib NDA. The absence of any insider-trading allegations further undermines any inference of scienter.

- **Lead Plaintiffs cannot plead that they reasonably relied on CTI's and Bianco's alleged misrepresentations and omissions.** The CAC fails to plead reasonable reliance because (i) no *Affiliated Ute* reliance presumption applies (Lead Plaintiffs allege both misrepresentations and omissions, and *Affiliated Ute* applies only in omission cases); (ii) the efficient-market reliance presumption applies only with regard to material misstatements and omissions (as described above, however, the allegedly concealed IDMC-related information was immaterial); and (iii) Lead Plaintiffs could not have actually relied on any IDMC-related misrepresentations or omissions before September 23, 2015 (neither CTI nor Bianco made IDMC-related statements before that date).

- **The CAC alleges no facts showing that CTI's and Bianco's alleged conduct caused Lead Plaintiffs' loss.** The CAC alleges that Lead Plaintiffs' losses were caused by February 8 and 9, 2016 CTI press releases that, according to the CAC, revealed the truth about pacritinib's development. But the press releases disclosed partial-hold and hold decisions by the FDA, and the CAC alleges no regulatory-approval-related misrepresentations or omissions by CTI or Bianco. Moreover, the press releases stated that the FDA's decisions were based primarily on (i) safety concerns relating to PERSIST-1 post-24-week "crossover" data (which CTI had previously disclosed as a potential issue); and (ii) newly released PERSIST-2 data (and Lead Plaintiffs allege no PERSIST-2-related misrepresentations or omissions).

The Securities Act claim against the Section 11 Individual Defendants fails for the additional reason that none executed a CTI registration statement containing alleged pacritinib-related misrepresentations or omissions. In fact, the November 2014 shelf-registration statement that the Section 11 Individual Defendants executed contains *no* statements describing the pacritinib clinical trials.

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STATEMENT OF FACTS[2]

CTI and Pacritinib

CTI is a publicly traded biopharmaceutical company founded in 1991 by two oncologists.[3] CTI focuses on the acquisition, development, and commercialization of therapies for blood-related cancers, with an emphasis on treatments that target cancers where there is currently an unmet medical need.[4]

Pacritinib, one of CTI's pipeline therapies, is an oral medication that treats myelofibrosis, a relatively rare blood-related cancer that affects hundreds of thousands of people.[5] Although there are available therapies, CTI developed pacritinib to potentially offer an advantage over alternatives by treating symptoms with less treatment-emergent thrombocytopenia (i.e., platelet deficiencies) and anemia.[6] In August 2014, the FDA granted pacritinib "Fast Track" designation for certain types of myelofibrosis, which expedites review of drugs that treat serious conditions or fill an unmet medical need.[7]

As of early 2015, pacritinib had progressed successfully to Phase III clinical trials—the

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[2] The facts are drawn from the CAC and the documents attached to the accompanying declaration of Leah Godesky, Esq., which were cited in the CAC or obtained from (i) the SEC's public Edgar database; (ii) the FDA's or EMA's agency websites; or (iii) CTI's website, in the case of one press release. Because the documents referenced in the CAC "have essentially been adopted as part of the complaint, the Court may consider them without converting the motion to dismiss into a motion for summary judgment. Once a document is deemed incorporated by reference, the entire document is assumed to be true for purposes of a motion to dismiss, and both parties—and the Court—are free to refer to any of its contents." *City of Roseville Emps.' Ret. Sys. v. Sterling Fin. Corp.*, 963 F. Supp. 2d 1092, 1107 (E.D. Wash. 2013). And with regard to the documents obtained from public websites, the Ninth Circuit has instructed that "[a] court may take judicial notice of matters of public record without converting a motion to dismiss into a motion for summary judgment." *Skilstaf Inc. v. CVS Caremark Corp.*, 669 F.3d 1005, 1016 n.9 (9th Cir. 2012); *see also Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006) (SEC filings subject to judicial notice); *Paralyzed Veterans of Am. v. McPherson*, 2008 WL 4183981, at *5 (N.D. Cal. Sept. 9, 2008) ("It is not uncommon for courts to take judicial notice of factual information found on the world wide web. This is particularly true of information on government agency websites"); *Mauss v. NuVasive, Inc.*, 2016 WL 3681831, at *6 (S.D. Cal. Jul. 12, 2016) ("In securities cases, courts routinely take judicial notice of SEC filings, press releases, and other publicly available financial documents.").

[3] *See* Godesky Decl. Ex. 1 at 20.

[4] *See id.* at 41.

[5] *See id.* at 2; *see also* Godesky Decl. Ex. 2 at 5.

[6] *See* Godesky Decl. Ex. 1 at 2.

[7] *See id.* at 3.

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final clinical-trial stage before commercialization—and two Phase III trials were underway[8]:

- *PERSIST-1*. PERSIST-1 involved 327 myelofibrosis patients who were randomized into two study arms, with twice as many patients receiving pacritinib as received the BAT.[9] Patients were permitted to "crossover" voluntarily from the BAT to pacritinib after 24 weeks of treatment.[10] PERSIST-1's primary "endpoint" (i.e., the goal around which the trial was randomized and powered) was achieving a 35% reduction in spleen volume after 24 weeks.[11] Enrollment was completed in August 2014.[12]

- *PERSIST-2*. The second pacritinib Phase III trial targeted up to 300 myelofibrosis patients with low blood-platelet counts.[13] Like PERSIST-1, the trial compared pacritinib to the BAT.[14] Enrollment in PERSIST-2 continued throughout 2015.[15]

CTI Engages An IDMC To Consult On Pacritinib's Development.

CTI engaged voluntarily an IDMC to consult on pacritinib's development. A clinical-trial IDMC is a group of individuals with relevant expertise that reviews data from ongoing clinical trials, and advises the sponsor on the trial's safety, validity, and scientific merit.[16] An IDMC's recommendations are purely advisory; the "FDA will rarely, if ever, tell a sponsor which decision to make" in response to IDMC recommendations.[17] FDA guidance, for example, provides that "the sponsor decides whether to accept [IDMC] recommendations to discontinue a trial."[18] The EMA's guidelines similarly state that "the implementation of any [I]DMC recommendation is solely the responsibility of the sponsor[,] who is free to reject (in whole or part) recommendations."[19] CTI's IDMC charter therefore stated specifically that CTI had final

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[8] *See id.* at 7.

[9] *See id.*

[10] *See* Godesky Decl. Ex. 3 at 2 ("The design of PERSIST-1 and PERSIST-2 allows for patients on the BAT arm to crossover and receive treatment with pacritinib if their disease progresses or after they achieve the 24-week measurement endpoint.").

[11] *See* Godesky Decl. Ex. 1 at 7.

[12] *See* Godesky Decl. Ex. 4 at 2.

[13] *See* Godesky Decl. Ex. 1 at 7.

[14] *See id.*

[15] *See id.* at 8.

[16] *See* Godesky Decl. Ex. 18 at 1.

[17] *Id.* at 33.

[18] *Id.*

[19] Godesky Decl. Ex. 19 at 6.

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decision-making authority with regard to all IDMC recommendations.[20]

In February 2015, the IDMC identified preliminarily non-statistically significant safety issues relating to BAT patients who crossed over to pacritinib after 24 weeks of treatment.[21]

CTI Pursues Further Evaluation of PERSIST-1 Data.

Between March and June 2015, CTI and its partners commissioned a number of independent analyses of the PERSIST-1 data.[22]

- *PERSIST Steering Committee Review*. CTI's PERSIST Steering Committee was comprised of external experts and the studies' principal investigators.[23] After reviewing the PERSIST-1 data, the Steering Committee disagreed with the IDMC, and concluded that the pacritinib trials should continue as planned.[24]

- *Review By Independent Clinician and Statistician Engaged By CTI*. CTI separately engaged an independent statistician and clinician experienced in clinical-trial-safety oversight to evaluate pacritinib's PERSIST-1 safety profile.[25] Neither was informed of the IDMC's or the Steering Committee's conclusion, and both experts determined that the pacritinib trials should continue as planned.[26]

- *Review By Independent Statistician Engaged by IDMC Firm.* The firm that CTI engaged to assemble the IDMC also hired an independent statistician to evaluate the IDMC's analyses and recommendations.[27] The statistician concluded there was no need to terminate or hold enrollment in the pacritinib studies.[28]

Concerns about the IDMC's impartiality arose in view of the otherwise unanimously favorable review of the PERSIST-1 data, and CTI decided to retain a new IDMC through an independent firm specializing in assembling IDMCs.[29] The newly constituted IDMC recommended that the

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[20] *See* Godesky Decl. Ex. 5 at 16.

[21] *See* Godesky Decl. Ex. 6 at 17; *see also* Godesky Decl. Ex. 5 at 16.

[22] *See* Godesky Decl. Ex. 6 at 17.

[23] *See* Godesky Decl. Ex. 5 at 16.

[24] *See id.*

[25] *See id.*

[26] *See id.*

[27] *See id.*

[28] *See id.*

[29] *See id.*

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pacritinib trials continue as planned.[30]

CTI Cautions Investors That PERSIST-1 Results May Not Lead To FDA Approval.

In March 2015, CTI announced publicly top-line primary-endpoint PERSIST-1 results, and reported that PERSIST-1 met its primary endpoint.[31] CTI's March 9, 2015 press release cautioned, however, that its announcement was "subject to a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results and the trading price of [CTI's] securities."[32] "In particular," CTI warned, the announcement only "address[ed] top-line results regarding primary endpoints," and should be reevaluated when additional "data has been more fully analyzed."[33]

The SEC annual report that CTI filed a few days later reiterated CTI's March 9 disclosures. As a general matter, CTI cautioned investors that "[s]uccessful development of anti-cancer and other pharmaceutical products is highly uncertain, and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and speculative."[34] Thus, "[c]ompounds that appear promising in research and development may fail to reach later stages of development for a number of reasons," including "suspension of a clinical trial at any time by [CTI] . . . or a regulatory authority on the basis that the participants are exposed to unacceptable health risks or for other reasons."[35] With regard to PERSIST-1, CTI cautioned specifically that the top-line results reported earlier that month "may differ from future results, or different conclusions or considerations may qualify such results once existing data has been more fully evaluated."[36] Importantly, CTI explained, "third parties, including regulatory agencies, may not accept or

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30 *See id.*

31 *See* Godesky Decl. Ex. 2 at 2.

32 *Id.* at 5.

33 *Id.* at 5-6.

34 Godesky Decl. Ex. 1 at 22.

35 *Id.* at 22-23.

36 *Id.* at 23.

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agree with [CTI's] assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program [or] the approvability . . . of the particular compound."[37] Thus, CTI further warned, CTI "may not be able to obtain approval of any of [its] products . . . at all."[38] CTI repeated these warnings in its May 6, August 6, and November 5, 2015 SEC filings.[39]

CTI Discloses Communications With The FDA Seeking Further Guidance On The "Crossover" Issue.

In July 2015, CTI requested a meeting with the FDA to determine whether the FDA concurred with CTI's decision to continue the pacritinib trials.[40] In support of its decision to proceed with the pacritinib trials as planned, CTI provided the FDA with all the information reviewed by the original IDMC, the IDMC's meeting minutes, and the written opinions of the Steering Committee, CTI's external experts, and the statistician engaged by the IDMC firm.[41] The FDA's written response stated that although it had not yet reviewed the data, it is generally difficult to draw meaningful conclusions from non-statistically significant results,[42] and PERSIST-1's "crossover" design may exacerbate that difficulty.[43] The FDA response neither instructed nor required clinical-trial modifications or holds.[44]

On September 23, 2015, CTI told investors in a press release that CTI planned to submit an NDA to the FDA later that year.[45] CTI's press release and subsequent SEC Form 10-Q filing

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37 *Id.*

38 *Id.*

39 *See* Godesky Decl. Ex. 7 at 28-29 ("Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all."); Godesky Decl. Ex. 8 at 34-35 (same); Godesky Decl. Ex. 6 at 33-34 (same).

40 *See* Godesky Decl. Ex. 5 at 16.

41 *See id.*; *see also* Godesky Decl. Ex. 6 at 17.

42 *See* Godesky Decl. Ex. 5 at 16.

43 *See id.*

44 *See id.*

45 Godesky Decl. Ex. 3 at 2.

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cautioned that PERSIST-1's crossover design "may confound evaluation of survival," and explained that the IDMC "in place at the time" had previously "recommended patients on the [BAT] arm . . . not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks."[46] But "[a]fter receiving input from external independent experts and sending the FDA the PERSIST-1 data," CTI explained, it had "notified the FDA of the decision to proceed per protocol."[47] CTI warned that while it had "determined that no modifications to the ongoing trials were required,"[48] any statements relating to pacritinib's development are "subject to a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results and the trading price of [CTI's] securities," including CTI's statements regarding "plans and intentions with respect to the submission of an NDA."[49] Indeed, CTI cautioned, its "NDA requesting accelerated approval for pacritinib may not be accepted by the FDA."[50]

CTI's Stock Offering.

In October and December 2015, CTI issued over $100 million in new shares of preferred stock under a November 21, 2014 Form S-3 shelf-registration statement.[51] The prospectus supplements for the offerings repeated CTI's September 2015 disclosures regarding its decision to proceed with the pacritinib trials based on all available data, despite the IDMC's concerns arising out of "crossover"-related safety issues.[52] CTI also warned that any future announcements regarding "results of clinical trials and regulatory actions" could have a "significant" effect on market price.[53]

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46 *Id.* at 3; *see also* Godesky Decl. Ex. 6 at 17.

47 Godesky Decl. Ex. 3 at 3; *see also* Godesky Decl. Ex.6 at 17.

48 Godesky Decl. Ex. 3 at 3.

49 *Id.* at 3-4.

50 *Id.* at 4.

51 Godesky Decl. Ex. 9; *see also* CAC ¶¶ 62, 70.

52 *See* Godesky Decl. Ex. 10 at S-8; *see also* Godesky Decl. Ex. 11 at S-8.

53 *See* Godesky Decl. Ex. 10 at S-17; *see also* Godesky Decl. Ex. 11 at S-17.

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The FDA Places Pacritinib Development On Hold.

In December 2015, CTI submitted an NDA to the FDA seeking approval to market pacritinib in the United States to myelofibrosis patients with no treatment options.[54] On February 4, 2016, the FDA placed a partial clinical hold on pacritinib in view of excess mortality and other adverse events that were most evident during the post-24-week "crossover" period.[55] CTI disclosed the FDA's partial clinical hold on February 8, 2016.[56] Later that day, the FDA notified CTI that the FDA had decided to place pacritinib on a full clinical hold, which CTI disclosed the next day.[57] CTI's February 9 press release explained that the FDA's full-hold decision was based on additional "interim overall survival results from PERSIST-2."[58]

The FDA Removes The Pacritinib Clinical Hold.

On January 5, 2017, CTI announced the FDA's decision to lift the clinical hold on pacritinib.[59] The FDA removed the hold order based on its review of final clinical-study reports for the PERSIST-1 and PERSIST-2 trials, and CTI anticipates commencing a pacritinib dose-exploration trial involving nearly 100 patients in early 2017.[60]

ARGUMENT

I. LEAD PLAINTIFF'S SECURITIES-FRAUD CLAIMS SHOULD BE DISMISSED (Counts IV-V).

To prevail on a claim for violations of Section 10(b) or Rule 10b-5, a plaintiff must prove (i) a material misrepresentation or omission; (ii) that the defendant made with scienter; (iii) on which the plaintiff reasonably relied; and (iv) that caused plaintiff's alleged loss. *See In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1052 (9th Cir. 2014). A plaintiff cannot prevail on a

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54 *See* Godesky Decl. Ex. 5 at 15.

55 *See* Godesky Decl. Ex. 12 at 2.

56 *See id.*

57 *See* Godesky Decl. Ex. 13 at 2.

58 *Id.*

59 *See* Godesky Decl. Ex. 20 at 2.

60 *See id.*

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claim under Section 20(a)—which establishes control-person securities-fraud liability—unless the plaintiff first proves a primary violation of Section 10(b). *See id.*

The CAC alleges that CTI and Bianco misrepresented (i) that pacritinib's Phase III safety profile was consistent with or better than its Phase II safety profile; (ii) that there was limited Phase III discontinuation of pacritinib based on gastrointestinal side effects; (iii) that pacritinib controls disease-related symptoms better than alternative therapies; (iv) that CTI disclosed the "most important" top-line PERSIST-1 data; and (v) the IDMC's pacritinib recommendation. *See* Appendix A. The CAC also alleges that CTI and Bianco concealed (i) a PERSIST-1 imbalance in pre-24-week adverse events and deaths across the pacritinib and BAT arms; and (ii) information relating to the IDMC's recommendation and discharge.[61] None of these allegations states a securities-fraud claim for the reasons described below.

A. The CAC Fails To Plead Scienter By CTI or Bianco.

Under the PSLRA, dismissal of a securities-fraud claim is required in the absence of "facts raising a strong inference that the statements were intentionally false, misleading, or made with deliberate recklessness." *Ronconi*, 253 F.3d at 432. Deliberate recklessness is "an *extreme departure* from the standards of ordinary care . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). "To allege a strong inference of deliberate recklessness," a complaint "must state facts that come closer to demonstrating intent, as opposed to mere motive and opportunity." *Dsam Glob. Value Fund v. Altris Software*, 288 F.3d 385, 389 (9th Cir. 2002). Ninth Circuit courts apply a two-step scienter inquiry that (i) first examines "whether any of the plaintiff's allegations, standing alone, is sufficient to create a strong inference of scienter"; and (ii) "[if] none is sufficient alone, . . .

[61] *See, e.g.*, CAC ¶ 146 (alleging that CTI and Bianco concealed that (i) "the IDMC recommended that CTI terminate the PERSIST-1 study and stop enrollment in PERSIST-2 due to concerns about patient deaths on pacritinib"; and (ii) "CTI did not follow the IDMC's recommendation to stop the studies"); *id.* ¶ 149 (same); *id.* ¶ 155 (same, plus allegation that CTI and Bianco concealed that CTI "decided to discharge the IDMC due to supposed concerns about the impartiality of the original IDMC"); *id.* ¶ 164 (same).

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consider[s] the allegations holistically to determine whether they create a strong inference of scienter taken together." *NVIDIA*, 768 F.3d at 1056. "This is not an easy standard to comply with—it was not intended to be—and plaintiffs must be held to it." *Eminence Cap., LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).

As described below, the CAC's five categories of scienter-related allegations fail—independently and together—to give rise to a strong inference that CTI or Bianco engaged in an "extreme departure" from ordinary standards of care, and Lead Plaintiffs' Section 10(b) claim must be dismissed on that basis.

1. No single allegation sufficiently pleads scienter.

a. Allegations relating to pacritinib's economic importance are insufficient.

None of the CAC's three conclusory assertions regarding pecuniary benefit to CTI and Bianco are sufficient to plead scienter.

- *The importance of pacritinib to CTI's economic success*. The CAC alleges that pacritinib was critical to CTI's financial health, and that CTI and Bianco "were motivated by unique milestone payments and the terms of an advance that were contingent on positive results from the pacritinib trials."[62] But "[i]f simple allegations of pecuniary motive were enough to establish scienter, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions." *Zucco*, 552 F.3d at 1005. These "[g]eneralized assertions of financial motive, without more, are insufficient to meet the heightened pleadings requirement of the PSLRA." *Verona Partners, LLC v. Tenet Capital Partners Convertible Opportunities Fund, LP*, 2006 WL 2669035, at *12 (N.D. Cal. Sept. 18, 2006).

- *Bianco's receipt of bonuses and compensation*. The CAC's claim that Bianco received bonuses and compensation as a result of the alleged fraud[63] is also insufficient to plead scienter because "it is common for executive compensation, including stock options and bonuses, to be based partly on the executive's success in achieving corporate goals." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 884 (9th Cir. 2012). Thus, courts in the Ninth Circuit "will not conclude that there is fraudulent intent merely because a defendant's compensation was based in part on such successes." *Id.* Moreover, the

[62] CAC ¶ 136; *see also id.* ¶ 126 ("The results of PERSIST-1 were critical to the Company's financial well-being."); *id.* ¶ 131 ("Defendant Bianco knew that investor and analyst attentions were acutely focused on the results of the PERSIST-1 study and pacritinib's safety profile.").

[63] *See* CAC ¶ 133 ("Defendant Bianco received substantial bonuses and compensation as a result of his misrepresentations and omissions.").

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CAC's conclusory allegations "fail[] to provide specifically, with comparisons to prior years bonuses, the correlation between [Bianco's] compensation and [CTI's] bottom line." *Zucco*, 552 F.3d at 1005 (rejecting "bare assertion that executive-level bonuses were based in part on [company's] financial performance").

- *CTI's October and December 2015 stock offerings*. The CAC alleges that scienter is demonstrated by CTI's 2015 stock offerings.[64] But a "desire[] to obtain favorable financing" is an "ordinary and appropriate corporate objective[]," and thus insufficient to establish a strong inference of scienter. *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002). "[T]o hold otherwise would support a finding of scienter for any company that seeks to enhance its business prospects." *Rigel*, 697 F.3d at 884 ("[A]llegations of routine corporate objectives such as the desire to obtain good financing" insufficient to allege scienter).

Moreover, the CAC alleges no insider trading by Bianco. The absence of suspicious insider class-period stock sales "is inconsistent with [the CAC's] theory that financial motive establishes scienter here"; "[i]n fact, it supports the *opposite* inference." *Id.* at 885.

b. Executive-departure allegations fail to establish a strong inference of scienter.

The CAC alleges scienter based on (i) eight CTI-executive departures over a nine-month period in 2015; and (ii) Bianco's October 2, 2016 resignation.[65] But the CAC states no facts comparing the alleged executive departures to CTI's typical hiring and termination patterns. And "[a]bsent allegations that the resignation[s] at issue [were] uncharacteristic when compared to [CTI's] typical hiring and termination patterns . . . the inference that [CTI] forced certain employees to resign because of its knowledge of the employee's role in the fraudulent representations will never be as cogent or as compelling as the inference that the employees resigned or were terminated for unrelated personal or business reasons." *Zucco*, 552 F.3d at 1002 (allegations regarding resignation of CFO, controllers, and independent-accounting firm insufficient to plead scienter). And the CAC pleads no facts regarding whether the departing

[64] *See* CAC ¶ 137 ("Defendant Bianco secured needed liquidity for his Company through stock offerings.").

[65] *See* CAC ¶ 138 ("At the same time that Defendants Bianco and CTI were touting pacritinib, CTI executives were quietly exiting the Company."); *id.* ¶ 139 ("Defendant Bianco abruptly left CTI after the disclosure of the clinical hold, IDMC's findings, and the SEC investigation.").

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executives were retirement age or if they left to pursue other opportunities. *See id.*

Moreover, "[c]orporate executives are held accountable for the corporation's financial performance; when that performance suffers, those executives are often replaced. Such is the order of things." *Roseville*, 963 F. Supp. 2d at 1139; *see also Zucco*, 552 F.3d at 1002 (observing accounting firm's resignation coincided with responsibility for "corporation's failure to adequately control accounting procedures"). Bianco resigned in the months following the FDA's clinical-trial hold decision and a substantial drop in CTI's share price; the CAC pleads no facts supporting the inference that his "departure was attributable to anything other than personal accountability for [CTI's] poor financial performance." *Roseville*, 963 F. Supp. 2d at 1138.

c. Allegations regarding the SEC investigation are insufficient.

Similarly unavailing is the CAC's attempt to plead scienter based on CTI's alleged nondisclosure of (i) an October 23, 2015 letter from the SEC to the FDA requesting pacritinib-related files[66] (because the CAC pleads no facts showing that CTI or Bianco had knowledge of the SEC's letter); or (ii) a January 2016 SEC subpoena to CTI seeking documents relating to the PERSIST trials[67] (because "the securities laws do not impose an obligation on a company to predict the outcome of investigations," "[t]here is no duty to disclose litigation that is not substantially certain to occur," *see In re Lions Gate Entm't Corp. Sec. Litig.*, 165 F. Supp. 3d 1, 12 (S.D.N.Y. 2016)).

d. A May 2015 Power Point presentation fails to give rise to a strong inference of scienter.

No inference of scienter arises from the CAC's claim that a May 30, 2015 Power Point misleadingly presented PERSIST-1 mortality data through January 15, 2015, rather than through 24 weeks of treatment.[68] *First*, the Power Point disclosed accurately the date ranges associated

[66] *See* CAC ¶ 135.

[67] *See id.*

[68] *See* CAC ¶ 134.

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with the data, and there was nothing misleading about the statement that mortality was "as of data cut off: January 17, 2015."[69] *See Philco Invs., Ltd. v. Martin*, 2011 WL 500694, at *8-9 (N.D. Cal. Feb. 9, 2011) (dismissing securities-fraud claim because "[t]hough the release did not contain all of the detail Plaintiffs would have liked, it was not misleading"). *Second*, despite the CAC's conclusory claim that CTI used a January 17, 2015 cutoff to conceal that "twice the percentage" of pacritinib-treated patients died within the first 24 weeks of therapy, the pleaded facts demonstrate that the allegedly concealed "imbalance" was not statistically significant. The allegedly concealed data reflects that 5% of pactrinib-treated patients and 3% of BAT-treated patients died within the first 24 weeks of treatment.[70] *See id.* at *5 (dismissing complaint that "fail[ed] to explain the significance of the [undisclosed information] either statistically or medically"). *Third*, allegations of insufficient disclosure of *pre*-24-week data fail to give rise to a strong inference of scienter, because the February 2015 IDMC recommendation and February 2016 FDA-hold decisions were based primarily on *post*-24-week mortality and adverse-event data.[71]

e. The CAC fails to plead scienter based on CTI's and Bianco's knowledge of PERSIST-1 data and response to the IDMC recommendation.

Finally, the CAC's allegations relating to CTI's and Bianco's knowledge of the PERSIST-1 data and response to the February 2015 IDMC recommendation[72] are insufficient to plead scienter because the CAC fails to plead facts demonstrating a link between CTI's and

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[69] *See* Godesky Decl. Ex 14 at 5.

[70] *See* CAC ¶ 41 (alleging 11 of the 220 pacritinib patients died within the first 24 weeks, compared to 3 of the 107 BAT patients).

[71] *See* Godesky Decl. Ex. 12 at 2 ("The excess mortality was most evident during the non-randomized crossover period *following* the initial 24 weeks of randomized treatment.").

[72] *See* CAC ¶ 124 ("By the start of the Class Period, CTI and Bianco knew of the IDMC's findings and recommendation."); *id.* ¶ 127 ("Defendant Bianco had intimate knowledge of the PERSIST-1 study results."); *id.* ¶ 130 ("Defendant Bianco spoke repeatedly about the results of the PERSIST-1 study and pacritinib's safety profile."); *id.* ¶ 132 ("Federal regulations required CTI and Bianco to monitor the PERSIST-1 trials and report patient deaths."); *id.* ¶ 125 (referencing "Bianco and CTI's response to the IDMC's findings and recommendations."); *id.* ¶ 129 (alleging "Bianco and CTI's 'discharging' of the members of the IDMC.").

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Bianco's knowledge of the PERSIST-1 data and their alleged knowledge that the PERSIST-1 mortality and adverse-event data was deficient. In *Gompper v. VISX, Inc.*, for example, the Ninth Circuit considered a securities-fraud claim where the plaintiff alleged that "defendants intentionally or recklessly misrepresented the truth when they made optimistic statements about [the company's] future earnings and growth," even though defendants allegedly "knew its patents were invalid." 298 F.3d 893, 895-96 (9th Cir. 2002). Although the complaint "adequately demonstrate[d] the defendants were unquestionably aware of [a] claim against one of their core patents," the Ninth Circuit dismissed the complaint because "in the end[,] it fail[ed] to demonstrate the link between awareness of the claim and knowledge that the patents were therefore invalid." *Id.* To the contrary, the court explained, the defendants "fervently believed in the viability of the patent portfolio, and litigated its defense with ferocity." *Id.* The same principles apply in the pharmaceutical drug-approval context. As the United States District Court for the Southern District of New York recently explained, "[t]here is no inconsistency between a pharmaceutical company executive's concern about adverse events and the possibility of a negative FDA reaction to a proposed drug, and his sincere optimism that the FDA was likely to approve the drug." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 533 (S.D.N.Y. 2015).

Here, the CAC alleges *no facts* demonstrating that CTI and Bianco *actually believed* that the pacritinib mortality and adverse-event data would prevent regulatory approval. Rather, as described in more detail below, CTI and Bianco "fervently believed," *Gompper*, in the viability of the PERSIST-1 data. In the absence of facts "showing that there was a consensus of the management that the risks of [pacritinib] made the drug unlikely to be approved," the CAC's conclusory scienter allegations must be dismissed. *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008).

2. The CAC does not holistically plead scienter.

In analyzing scienter allegations holistically, "the court must also take into account plausible opposing inferences that could weigh against a finding of scienter." *Wozniak v. Align*

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Tech., Inc., 850 F. Supp. 2d 1029, 1045 (N.D. Cal. 2012). The "inference of scienter must be strong in light of other explanations, and a court must consider plausible nonculpable explanations for the defendant's conduct." *Philco*, 2011 WL 500694, at *5. "A number of cases have dealt with the situation of a pharmaceutical company attempting to develop a drug which ultimately cannot be placed on the market or is taken off the market." *AstraZeneca*, 559 F. Supp. 2d at 470. "The key, of course," is whether there is an "honest belief of the management in the truth of information issued to the public"; only if "management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public" is there scienter. *Id.*

Here, as explained above (*see supra* pp. 16-17), the CAC pleads no facts demonstrating that CTI or Bianco knew the PERSIST-1 data would prevent pacritinib's regulatory approval. After their receipt of a non-binding, preliminary IDMC recommendation, CTI and Bianco reasonably determined that further analysis was warranted. *See Philco*, 2011 WL 500694, at *5 (determining "more likely motive" for nondisclosure of side-effect issues was "a desire to avoid creating unfounded panic among patients, doctors, and the market"). They commissioned additional review by pacritinib's Steering Committee, two independent statisticians, and an independent clinician. *See supra* pp. 6-7. CTI and Bianco discharged the IDMC only after those independent experts unanimously rejected the IDMC's recommendation, and the newly constituted IDMC recommended that the pacritinib trials continue as planned. *See supra* pp. 6-7. When CTI and Bianco contacted the FDA to seek its concurrence, they sent the FDA all available data and analysis, including the original IDMC's conclusions. *See supra* pp. 8-9. CTI and Bianco made *no* public assurances regarding the likelihood of regulatory approval, and CTI's disclosures identified the IDMC's "crossover" concerns and subsequent independent-data review while warning that the NDA may be rejected. *See supra* pp. 9-10. Meanwhile, CTI continued to invest in pacritinib's development, and Bianco retained the majority of his stock

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holdings.[73]

The reasonableness of CTI's and Bianco's belief that pacritinib is a safe and efficacious therapy that will eventually obtain regulatory approval is further demonstrated by the FDA's recent decision to lift the February 2016 clinical hold on pacritinib.[74] *See Kovtun v. VIVUS, Inc.*, 2012 WL 4477647, at *10 (N.D. Cal. Sept. 27, 2012) (noting "significance" of FDA's post-class-period approval of drug because "it vitiates plaintiff's theory . . . that defendants knew . . . side effects presented a real, immediate and known risk that [drug] *could not and would not be approved by the FDA* based on the existing safety data) (emphasis in original); *see also In re MELA Scis., Inc. Sec. Litig.*, 2012 WL 4466604, at *13-14 (S.D.N.Y. Sept. 19, 2012) (noting in finding no actionable omissions that "FDA eventually approved [drug] at least in part based on the results of the clinical trial" at issue).

The most compelling inference is therefore that CTI and Bianco reasonably believed that the PERSIST-1 data would favorably support an NDA, and that the IDMC's recommendation was erroneous. *See Wozniak*, 850 F. Supp. 2d at 1045-46 ("The more compelling inference is that [defendant], without any intent to defraud, simply failed to accurately predict the precise effects that [certain things] would have on new revenue cases."); *see also In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1425 (9th Cir. 1994) (no scienter where executive officers increased expenditures on advertising and product development); *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1118 (9th Cir. 1989) (any inference of bad faith "completely dispelled" by defendants' decision to "stake much of [the company's] future on the success of" product while "retain[ing] the great bulk of their [company] holdings"). Because "there is no basis to conclude that defendants characterized the results of the [PERSIST-1] clinical trial . . . in a manner inconsistent with what they believed to be the truth," the Section 10(b) claim must be dismissed. *MELA Scis.*, 2012 WL 4466604, at *13.

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[73] *See, e.g.*, Godesky Decl. Ex. 6 at 7; *see also* Godesky Decl. Exs. 15 and 16 (Bianco SEC Form 4s reflecting 3,501,576 shares as of January 9, 2015 and 2,148,302 shares as of February 18, 2016).

[74] *See* Godesky Decl. Ex. 20 at 2.

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B. The CAC Pleads No Actionable Misrepresentations Or Omissions.

"At the pleading stage, a complaint stating claims under section 10(b) and Rule 10b-5 must satisfy the dual pleading requirements of Federal Rule of Civil Procedure 9(b) and the PSLRA." *Rubke v. Capitol Bancorp Ltd*, 551 F.3d 1156, 1164 (9th Cir. 2009). Thus, a Section 10(b) claim must be dismissed, unless a material misrepresentation or omission is pleaded with particularity. *See id.*

As described in more detail below, Lead Plaintiffs' Section 10(b) claim cannot survive the pleading stage because (i) the CAC fails to plead particularized facts demonstrating the falsity of alleged misrepresentations relating to PERSIST-1 data; (ii) the CAC fails to identify a statement rendered misleading by the alleged failure to disclose a post-24-week PERSIST-1 imbalance in mortality and adverse-event data; (iii) CTI disclosed its IDMC-discharge decision; and (iv) the allegedly misrepresented and concealed IDMC-related information was immaterial.

1. The CAC Fails To Plead Particularized Facts Demonstrating The Falsity Of Alleged Misrepresentations Relating To PERSIST-1 Data.

"A securities fraud claim cannot survive a motion to dismiss . . . merely by alleging that certain statements were false." *In re Am. Apparel, Inc. S'holder Litig.*, 855 F. Supp. 2d 1043, 1065 (C.D. Cal. 2012). Rather, under the PSLRA and Rule 9(b), "a plaintiff must plead falsity with particularity . . . [by] specify[ing] each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." *Rubke*, 551 F.3d at 1164; *see also* 15 U.S.C. § 78u-4(b)(1). In *In re Silicon Storage Technology, Inc. Securities Litigation*, for example, the United States District Court for the Northern District of California dismissed a Section 10(b) claim on the ground that the plaintiffs failed to "state[] with particularity *why* each statement was false at the time it was made." 2006 WL 648683, at *6-7 (N.D. Cal. Mar. 10, 2006). The plaintiffs claimed that valuations reflected in the defendant's quarterly financial reports were inaccurate, but the complaint "contain[ed] no allegations of contemporaneous conditions or statements . . . that contradict[ed] [defendant's] statements." *Id.* at *7; *see also In re Pixar Sec.*

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Litig., 450 F. Supp. 2d 1096, 1101 (N.D. Cal. 2006) (dismissing Section 10(b) claim for failure to plead facts showing alleged statements were false or misleading).

There are no facts in the CAC showing that CTI's and Bianco's alleged statements about PERSIST-1 data were false.

- *Alleged misrepresentations relating to pacritinib's gastrointestinal side effects and control of disease-related symptoms.*[75] The CAC alleges that CTI's and Bianco's statements about gastrointestinal side effects and disease-related symptoms were false and misleading because "the PERSIST-1 results showed an imbalance in the rates of death and serious cardiac events between the two study arms."[76] But the alleged misrepresentations about gastrointestinal side effects and control of disease-related symptoms *have nothing to do with* mortality and adverse-event data.

- *Alleged false comparisons to Phase II clinical-trial results.*[77] The CAC states no reasons why CTI's and Bianco's alleged comparison of Phase II and III safety results was inaccurate. In fact, the CAC contains *no* particularized facts regarding Phase II results.

- *Bianco's statement regarding top-line results.*[78] Because the CAC pleads no facts identifying the categories of data included in CTI's March 2015 "top-line release," it fails to allege adequately the falsity of Bianco's March 9, 2015 statement that CTI disclosed the "most important" information in the top-line release.[79] Moreover, "[v]ague, generalized, and unspecific assertions of corporate optimism or statements of 'mere puffing' cannot state actionable material misstatements of fact under federal securities laws." *In re Cornerstone Propane Partners, L.P. Sec. Litig.*, 355 F. Supp. 2d 1069, 1087 (N.D. Cal. 2005). And Bianco's alleged reference to unidentified "most important" data is corporate puffery that is "not capable of objective verification." *Id.*; *see also In re NVE Corp. Sec. Litig.*, 551 F. Supp. 2d 871, 895 (D. Minn. 2007) (deeming referencing to "important" advances vague puffery).

The CAC's unparticularized misrepresentation allegations should be dismissed based on these fatal pleading deficiencies. *See Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1070 (9th Cir. 2008) (dismissing securities-fraud complaint where complaint's "explanation of how and why the statements were false [was] decidedly vague"); *see also Roseville*, 963 F. Supp.

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[75] *See* Appendix A.

[76] *See, e.g.*, CAC ¶¶ 145, 148.

[77] *See* Appendix A.

[78] *See* Appendix A.

[79] *See* CAC ¶ 143.

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2d at 1131 (dismissing securities-fraud claims because plaintiff failed to identify a "false or misleading . . . statement [by defendant that] was false or misleading at the time it was made").

2. The CAC's Allegations Regarding CTI's and Bianco's Alleged Nondisclosure Of PERSIST-1 Data And IDMC Discharge Are Insufficient.

a. The CAC's claim that CTI and Bianco concealed PERSIST-1 mortality and adverse-event data is not actionable.

"[I]t is well established that the PSLRA does not impose a duty of completeness." *City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1066 (N.D. Cal. 2012). Thus, Section 10(b) requires disclosure "only when necessary to make . . . other statements that were made, in the light of the circumstances under which they were made, not misleading." *Roseville*, 963 F. Supp. 2d at 1109.

The CAC identifies no CTI or Bianco statement that became misleading in view of their alleged failure to disclose an imbalance in 24-week mortality and adverse-event data between the pacritinib and BAT arms.[80] The only alleged prior CTI or Bianco "statement" that reflects *any* comparison of mortality and adverse-event data across the pacritinib and BAT arms is a single slide in a May 2015 Power Point.[81] But the slide clearly states that it reflects mortality and adverse-event data as of January 17, 2015, rather than 24 weeks.[82] In the absence of a 24-week-data disclosure that was rendered misleading by the alleged omission, Lead Plaintiffs' omission claim must be dismissed. *See Philco*, 2011 WL 500694, at *8 (explaining press release's "failure to state that there was no short-term advantage to taking [drug] did not render [press release] misleading, as it nowhere suggested that there *was* a short-term advantage").

b. CTI disclosed the IDMC discharge.

It is axiomatic that there is no actionable omission under Section 10(b) if the allegedly concealed information was actually disclosed. *See, e.g., Halperin v. eBanker USA.com, Inc.*, 295

[80] *See, e.g.*, CAC ¶¶ 146, 149, 155, 164.

[81] *See* Godesky Decl. Ex. 14 at 5.

[82] *See id.*

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F.3d 352, 361 (2d Cir. 2002) (upholding dismissal of securities-fraud complaint where "[t]he allegedly omitted facts were either disclosed or implied").

Here, contrary to Lead Plaintiffs' claim that CTI and Bianco concealed their decision to discharge and replace the pacritinib IDMC,[83] CTI's fall 2015 SEC Form 10-Q filing disclosed that the original IDMC had been replaced.[84] Thus, because "the allegedly omitted statements were actually disclosed, the § 10(b) claim fails." *Fried v. Lehman Bros. Real Estate Assocs. III, L.P.*, 2011 WL 1345097, at *10 (S.D.N.Y. Mar. 29, 2011).

3. CTI's And Bianco's Alleged IDMC-Related Misrepresentations and Omissions Are Not Material.

None of the alleged IDMC-related misrepresentations and omissions by CTI and Bianco (*see supra* p. 11) are actionable, because the CAC fails to plead the materiality of information relating to CTI's communications with and handling of the IDMC. *See, e.g.*, *Cement & Concrete Workers Dist. Council Pension Fund v. Hewlett Packard Co.*, 964 F. Supp. 2d 1128, 1141 (N.D. Cal. 2013) (dismissing claim for failure to plead materiality).

"To fulfill the materiality requirement, there must be a *substantial likelihood* that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Juniper Networks*, 880 F. Supp. 2d at 1066 (dismissing complaint for failure to plead facts demonstrating materiality). Federal courts around the country have long "held that there is no duty to disclose the results of FDA inspections that do not reflect final agency determinations." *Sanofi*, 87 F. Supp. 3d at 542. As the United States District Court for the Southern District of New York has explained, "[t]hese courts reasoned that interim FDA feedback is not material because it does not express a binding agency decision and is subject to change as the FDA and pharmaceutical companies work

[83] *See, e.g.*, CAC ¶ 155 (alleging that CTI concealed its decision to discharge the original IDMC).

[84] *See* Godesky Decl. Ex. 7 at 17 (stating that the IDMC "*in place at the time* for the PERSIST program" recommended no crossover).

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together to develop viable clinical trials and approvable licensing applications." *Id.*[85]

The same principle should apply with even more force to a pharmaceutical company's communications with and receipt of recommendations from an IDMC. If non-binding feedback and requests from the FDA—a regulatory agency with final decision-making authority—is immaterial as a matter of law, it necessarily follows that recommendations by voluntarily comprised IDMCs with no regulatory—or even decision-making—authority (*see supra* pp. 5-6) cannot be material. To hold otherwise would constitute a significant departure from current disclosure obligations, and impose on pharmaceutical companies a crushing obligation to disclose all goings-on behind the drug-development curtain. Managing such disclosure obligations amid clinical-trial work would be unduly burdensome and impractical—indeed, there is a slippery slope between nonbinding IDMC recommendations and nonbinding feedback from a single physician asked to review ad hoc interim clinical-trial data. Moreover, such disclosures would saturate the market. Investors would struggle to identify relevant information amid an avalanche of disclosures, and potentially act against their own interests in response to unreliable or irrelevant information. *See Twinde v. Threshold Pharms., Inc.*, 2008 WL 2740457, at *9 (N.D. Cal. Jun. 11, 2008) ("An excess of disclosure can have the same net effect as a dearth of it—the shareholder misses the relevant information").

[85] *See also In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("The Court finds Defendants, as a general proposition, had no duty to report its ongoing discussions with FDA during the review process."); *MELA Scis.*, 2012 WL 4466604, at *14 (no actionable omission based on failure to disclose FDA feedback expressing concerns about clinical trials, including concern that drug was "likely dangerous"); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, 2005 WL 4161977, at *7 (D. Colo. Oct. 20, 2005) (rejecting omission claim because "[t]he fact that the FDA staff members raised questions did not impose a duty upon the defendants to revise their opinions about the drug's efficacy or to report to the public the substance of their conversations with the FDA."); *In re Alkermes Sec. Litig.*, 2005 WL 2848341, at *16 (D. Mass. Oct. 6, 2005) (rejecting omission claim based on failure to disclose interim FDA request for additional studies to determine long-term effects of drug); *Fort Worth Emp'rs' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 227-28 (S.D.N.Y. 2009) (emphasizing in dismissing complaint that allegedly concealed FDA feedback was non-binding); *Sarafin v. BioMimetic Therapeutics, Inc.*, 2013 WL 139521, at *11 (M.D. Tenn. Jan. 10, 2013) ("The fact that the FDA told [defendant] to give 'serious consideration' to certain matters and said several things that should be done, does not mean that the approved protocol was somehow rejected.").

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C. The CAC Does Not Plead Reliance On CTI's and Bianco's Alleged Misrepresentations and Omissions.

The CAC fails to plead reasonable reliance on CTI's and Bianco's alleged misrepresentations and omissions because (i) no reliance presumption applies; and (ii) Lead Plaintiffs could not have actually relied before September 23, 2015 on CTI's and Bianco's alleged IDMC-related misrepresentations and omissions.

1. No Reliance Presumption Applies.

a. The reliance presumption based on material omissions is inapplicable.

The Ninth Circuit has instructed that a plaintiff's reliance on allegedly omitted facts should not be presumed under *Affiliated Ute Citizens v. United States*, 406 U.S. 128, 153-54 (1972), "unless the case can be characterized as one that primarily alleges omissions." *Binder v. Gillespie*, 184 F.3d 1059, 1064 (9th Cir. 1999). The *Affiliated Ute* presumption does not apply here because the CAC does not "primarily" allege omissions. Rather, it alleges that CTI and Bianco misrepresented five categories of information relating to PERSIST-1.[86] Courts in this circuit that are faced with a similar mix of misrepresentation and omission allegations routinely hold that the *Affiliated Ute* presumption is unavailable. *See, e.g.*, *Poulos v. Caesars World, Inc.*, 379 F.3d 654, 666 (9th Cir. 2010) ("mixed claims" not entitled to presumption); *Bondar v. Bank of Am. Corp.*, 2011 WL 740902, at *13-14 (N.D. Cal. Feb. 24, 2011) (same).

b. The efficient-market reliance presumption does not apply.

"[T]he fraud-on-the-market theory cannot apply absent a *material* misrepresentation or omission." *Amgen Inc. v. Conn. Ret. Plans and Trust Funds*, 133 S. Ct. 1184, 1195 (2013) (emphasis in original). That is because "immaterial information, by definition, does not affect market price, [and] cannot be relied upon indirectly by investors who, as the fraud-on-the-market theory presumes, rely on the market price's integrity." *Id.* And as described above (*see* pp. 22-23), the CAC fails to plead particularized facts demonstrating the materiality of CTI's and

[86] *See* Appendix A.

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Bianco's alleged IDMC-related misrepresentations and omissions.

2. Lead Plaintiffs Could Not Have Actually Relied Before September 23, 2015 On CTI's and Bianco's Alleged IDMC-Related Misrepresentations and Omissions.

Plaintiffs cannot plead reliance on an alleged misrepresentation if they could not have *actually relied* on the alleged statement. *See Tiberius Capital, LLC v. PetroSearch Energy Corp.*, 2011 WL 1334839, at *9 (S.D.N.Y. Mar. 31, 2011) (dismissing securities-fraud claim where "[p]laintiff never actually relied on Defendants' misrepresentation"). Indeed, even the efficient-market reliance presumption is only available to plaintiffs who can demonstrate that "the relevant transaction took place between the time the misrepresentations were made and the time the truth was revealed." *In re Diamond Foods, Inc. Sec. Litig.*, 295 F.R.D. 240, 247 (N.D. Cal. 2013).

The CAC alleges no pre-September 23, 2015 IDMC-related misrepresentations by CTI or Bianco. Thus, Lead Plaintiffs simply could not have purchased CTI securities in reliance on IDMC-related misstatements before that date, and any assertions of reliance that pre-date September 23, 2015 must be rejected.

D. The CAC Does Not Adequately Plead That CTI's and Bianco's Alleged Fraud Caused Lead Plaintiffs' Loss.

The purpose of securities-fraud actions is not "to provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause." *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 345 (2005). To plead loss causation, a complaint must show that the alleged "misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *In re Impax Labs., Inc. Sec. Litig.*, 2007 WL 5076983, at *3 (N.D. Cal. Jan. 3, 2007); *see also Nuveen Mun. High Income Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1119 (9th Cir. 2015) ("[P]laintiff must show that the revelation of [the] misrepresentation or omission was a substantial factor in causing a decline in the security's price"). An alleged corrective disclosure

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"must relate back to the misrepresentation and not to some other negative information about the company." *Bonanno v. Cellular Bomedicine Grp., Inc.*, 2016 WL 4585753, at *3 (N.D. Cal. Sept. 2, 2016). The disclosure of "[n]ew information is critical to demonstrating loss causation"; an alleged corrective disclosure cannot simply rehash information that was already disclosed to the market. *Bonanno v. Cellular Biomedicine Grp., Inc.*, 2016 WL 2937483, at *5 (N.D. Cal. May 20, 2016). Moreover, mere plausibility is not enough; to warrant discovery, loss-causation allegations must be pleaded with sufficient specificity to satisfy Rule 9(b). *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 605 (9th Cir. 2014) (extending 9(b)'s pleading requirements to loss-causation allegations).

The CAC alleges that Lead Plaintiffs' losses were caused by February 8 and 9, 2016 press releases that, according to the CAC, revealed the truth about pacritinib.[87] The CAC's loss-causation allegations are insufficient because the CAC identifies no "specific statements made by the Defendants that were made untrue or called into question by" the February 8 and 9, 2016 press releases. *Id.* at 608; *see also Nuveen*, 730 F.3d at 1120 (securities-fraud plaintiff must plead facts "showing that the defendant misrepresented or omitted the *very facts* that were a substantial factor in causing the plaintiff's economic loss") (emphasis in original). That is because the February 2016 press releases disclosed FDA partial and full-hold decisions for pacritinib. *See supra* p. 10. But the CAC alleges *no* misrepresentations by CTI and Bianco regarding the likelihood of pacritinib's regulatory approval. To the contrary, CTI and Bianco *warned* investors repeatedly of the risk that the FDA would not approve pacritinib for commercialization. *See supra* pp. 7-10.

Moreover, the information identified in the press releases as the basis for the FDA's hold decisions neither revealed new facts nor rendered false a prior CTI or Bianco statement.

- **February 8, 2016**. The February 8 press release stated that the FDA's partial-hold decision was based primarily on excess pacritinib-related mortality and adverse events

[87] *See* CAC ¶¶ 169-174 (alleging the "truth [was] revealed" based on the two press releases).

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during the PERSIST-1 post-24-week "crossover."[88] But CTI's fall and winter 2015 public statements had previously disclosed the IDMC's post-24-week "crossover" concerns.[89] The absence of new information in the February 8 press release is fatal to Lead Plaintiffs' loss-causation allegations. *See, e.g., Bonanno*, 2016 WL 4585753, at *5 (rejecting loss-causation allegations that failed to identify "new information" in corrective disclosures); *Jasin v. VIVUS, Inc.*, 2015 WL 3809357, at *8 (N.D. Cal. Jun. 18, 2015) (rejecting loss-causation allegations where "[p]laintiffs have not pled any facts to show that [alleged corrective disclosure] revealed . . . any new information").

- **February 9, 2016**. The February 9 press release stated that the FDA's hold decision was based on newly received PERSIST-2 data.[90] But the CAC pleads no misstatements relating to PERSIST-2. Because the press release renders no prior statement false, it does not qualify as a corrective disclosure. *See Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1208 n. 5 (9th Cir. 2016) (rejecting loss-causation allegations where the only new information identified in corrective disclosure failed to render prior statements false).

The CAC's failure to plead particularized facts showing that the specific alleged misrepresentations and omissions caused Lead Plaintiffs' loss requires dismissal of the Section 10(b) claim. *See Impax Labs.*, 2007 WL 5076983, at *3 (dismissing complaint for failure to plead loss causation); *see also Metzler*, 540 F.3d at 1063 (same).

E. The CAC's Failure To Plead A Section 10(b) Violation Requires Dismissal Of The Section 20(a) Claim.

Section 20(a) claims "may be summarily dismissed if a plaintiff fails to sufficiently plead a primary violation of [Section] 10(b)." *Roseville*, 963 F. Supp. 2d at 1106. Lead Plaintiffs' failure to plead a Section 10(b) violation thus warrants dismissal of Count V. *See Rigel*, 697 F.3d at 886 (dismissing Section 20(a) claim for failure to plead underlying violation).

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[88] *See* Godesky Decl. Ex. 12 at 2 ("In its written notification, the FDA cited the reasons for the partial clinical hold were that there was excess mortality and other adverse events in pacritinib-treated patients compared to the control arm in the PERSIST-1 trial. The excess mortality was most evident during the non-randomized crossover period following the initial 24 weeks of randomized treatment").

[89] *See, e.g.*, Godesky Decl. Ex. 6 at 17 (disclosing IDMC "recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks"); Godesky Decl. Ex 3 at 2-3 (same).

[90] *See* Godesky Decl. Ex. 13 at 2 ("The FDA's February 8, 2016, letter notes the interim overall survival results from PERSIST-2 show a detrimental effect on survival consistent with the results from PERSIST-1.").

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II. LEAD PLAINTIFFS' SECURITIES ACT CLAIMS SHOULD BE DISMISSED (Counts I-III).

To state a claim under the Securities Act of 1933, a plaintiff must identify a material misrepresentation or omission in a registration statement or prospectus. *See Rubke*, 551 F.3d at 1161 ("To prevail in [Section 11 case], a plaintiff must prove (1) that the registration statement contained an omission or misrepresentation, and (2) that the omission or misrepresentation was material").[91] A Section 11 claim must be dismissed if the defendant demonstrates "negative causation," i.e., that the alleged loss was not caused by the alleged misstatements or omissions. *See In re Shoretel Inc., Sec. Litig.*, 2009 WL 248326, at *4-6 (N.D. Cal. Feb. 2, 2009).

Lead Plaintiffs' Securities Act claims must be dismissed because, as described below, (i) the CAC fails to identify a material misrepresentation or omission in the shelf-registration statement (and, in any event, the alleged misrepresentations and omissions did not cause the alleged loss); (ii) the shelf-registration statement that Bianco and the Individual Section 11 Defendants executed contained no pacritinib-related statements; and (iii) Lead Plaintiffs' Section 15 claim fails in the absence of a primary Securities Act violation.

A. The CAC Fails To State A Section 11 or Section 12(a) Claim.

1. *Rule 9(b)'s Particularity Requirements Apply.*

"Although the heightened pleading requirements of the PSLRA do not apply to section 11 claims, plaintiffs are required to allege their claims with increased particularity under Federal Rule of Civil Procedure 9(b) if their complaint 'sounds in fraud.'" *Rubke*, 551 F.3d at 1161. To determine if a complaint "sounds in fraud," the court should determine if it alleges "a unified course of fraudulent conduct." *Id.* The same is true for Section 12(a) claims. *See Carol Gamble Tr. 86 v. E-Rex, Inc.*, 84 F. App'x 975, 978 (9th Cir. 2004) (Section 12(a) claims must be pleaded with particularity when "grounded in fraud"). A complaint sounds in fraud when it "employs the

[91] *See also* 15 U.S.C. § 77o (providing cause of action against persons who control others liable under Section 11); 15 U.S.C. § 77l (imposing liability for material misrepresentations or omissions in prospectus or oral communication).

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exact same factual allegations to allege violations of section 11 as it uses to allege fraudulent conduct under section 10(b) of the Exchange Act." *Rubke*, 551 F.3d at 1161.

Here, the facts alleged in support of Lead Plaintiffs' Section 11 and 12(a) claims are the same as the factual allegations underlying their Section 10(b) claim. As shown in Appendices B and C, the alleged Section 11 and 12(a) misrepresentation and omission allegations are exactly the same as the misrepresentations and omissions underlying the Section 10(b) claim. And all three claims are based on pacritinib-related statements in the same documents: CTI's October and December 2015 prospectus supplements and 2015 SEC filings.[92] Lead Plaintiffs' attempt to disclaim allegations of fraud with regard to their Securities Act claims is thus unconvincing, because "the gravamen of the complaint is plainly fraud." *In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1405 n.2 (9th Cir. 1996) (applying Rule 9(b)'s pleading standards to Section 11 claim); *see also Rigel*, 697 F.3d at 885 (rejecting "nominal efforts to disclaim allegations of fraud with respect to . . . section 11 claims"). Lead Plaintiffs' Securities Act claims must therefore be dismissed if the CAC fails to state with particularity the circumstances constituting the alleged fraud. *See id.*

2. The CAC Fails To State A Section 11 Or 12(a) Claim.

There are at least two reasons why Lead Plaintiffs' Section 11 and 12(a) claims must be dismissed. *First*, as described above, the CAC fails to particularize facts identifying a material misrepresentation or omission by CTI or Bianco in either the prospectus supplements or CTI's 2015 SEC filings. *See supra* Sections I.B-C. The Section 11 and 12(a) claims must be dismissed on this basis. *See Fresno Cty. Emps. Ret. Ass'n v. Alphatec Holdings, Inc.*, 607 F. App'x 694, 695 (9th Cir. 2015) (upholding district court's dismissal of Section 11 and 12(a)(2) claims "due to the lack of a false or misleading statement"); *see also Worlds of Wonder*, 35 F.3d at 1424 (upholding dismissal of Section 11 claim and observing that "the standard of materiality is the same under section 10(b) as it is under section 11"). And even if the Court concludes that the

[92] *See* Appendix B.

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Securities Act claims should be evaluated under Rule 8—which it should not, *see supra* pp. 28-29—the CAC's misrepresentation and omission allegations still fail to warrant discovery. Even under "Rule 8, conclusory allegations will not save a complaint from dismissal." *Brown v. Ambow Ed. Holding Ltd.*, 2014 WL 523166, at *3 (C.D. Cal. Feb. 6, 2014). And, as described above (*see supra* p. 20), the CAC's conclusory allegations fail to plausibly demonstrate the alleged misrepresentations' falsity. *See In re Wash. Mut., Inc. Sec., Derivative & ERISA Litig.*, 2010 WL 2545415, at *3 (W.D. Wash. Jun. 21, 2010) (complaint must be dismissed under Rule 8 unless it pleads "enough facts to state a claim to relief that is plausible on its face"). Like Section 10(b), the Securities Act contemplates omissions-based liability only if disclosure of the allegedly concealed information is necessary to make other statements not misleading, *see* 15 U.S.C. § 77k(a), and as shown above (*see supra* p. 21), the CAC identifies no statement that became misleading in view of the alleged failure to disclose an imbalance in pacritinib and BAT mortality and adverse events.[93] And the alleged failure to disclose CTI's decision to discharge and replace the pacritinib IDMC[94] is refuted directly by disclosures in the CTI November 5, 2015 Form 10-Q on which Lead Plaintiffs rely (*see supra* pp. 21-22). *See In re Violin Memory Sec. Litig.*, 2014 WL 5525946, at *9 (N.D. Cal. Oct. 31, 2014) ("[T]he Court is not required to accept as true conclusory allegations which are contradicted by documents referred to in the complaint.").

Second, Lead Plaintiffs' alleged loss was not caused by the alleged misrepresentations or omissions. As shown above (*see supra* Section I.D.), the February 8 and 9, 2016 press releases that Lead Plaintiffs claim caused their losses nowhere disclosed the alleged prospectus-supplement and SEC-filing misstatements and omissions. Rather, the alleged corrective disclosures merely disclosed information that was already in the market, or information that has nothing to do with the alleged misstatements. *See supra* p. 26-27. Defendants' negative-

[93] *See, e.g.*, CAC ¶ 77.

[94] *See, e.g., id.*

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causation defense thus requires dismissal of the Section 11 claim. *See Belodoff v. Netlist, Inc.*, 2009 WL 1293690, at *12 (C.D. Cal. Apr. 17, 2009) ("[F]ederal district courts have granted dismissal of Section 11 claims under Rule 12(b)(6) when the plaintiff's complaint has shown on its face that loss causation is not possible."); *see also Shoretel*, 2009 WL 248326, at *5 (rejecting contention that loss-causation arguments at motion-to-dismiss stage are premature).

B. Lead Plaintiffs' Claim Against The Section 11 Individual Defendants Fails As A Matter Of Law.

Section 11 extends liability to registration-statement signatories only when "any part of the registration statement, *when such part became effective*, contained an untrue statement of a material fact." 15 U.S.C. § 77k(a). Under SEC regulations, information in a prospectus supplement that post-dates a registration statement shall be deemed part of the registration statement as of the date the prospectus supplement is first used or the date of the first sale of securities under the prospectus supplement—whichever is earlier. *See* 17 C.F.R. § 230.430B(f)(1). But "that date *shall not* be an effective date as to any director of the issuer or any person signing any report or document incorporated by reference into the registration statement." *In re Countrywide Fin. Corp. Mortgage-Backed Sec. Litig.*, 932 F. Supp. 2d 1095, 1119 (C.D. Cal. 2013); *see also* 17 C.F.R. § 230.430B(f)(4)(i-ii).

The Section 11 Individual Defendants are not liable under Section 11 because the November 21, 2014 shelf-registration statement that they signed contains no alleged misstatements about pacritinib. In fact, the shelf-registration statement says *nothing* about the pacritinib clinical trials.[95] And SEC regulations instruct that the fall and winter 2015 CTI prospectus supplements on which Lead Plaintiffs' claim is based "shall not" be new effective dates for purposes of the individual defendants' Section 11 liability. *See* 17 C.F.R. § 230.430B(f)(4).[96] For these reasons, the claim against the Section 11 Individual Defendants

[95] *See* Godesky Decl. Ex. 9.

[96] The soundness of regulations precluding individual Section 11 liability where a prospectus supplement post-dates the registration statement is illustrated by the mid-Class Period departure from CTI of Defendant John

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should be dismissed in its entirety. *See Countrywide*, 932 F. Supp. 2d at 1119 (dismissing Section 11 claim against individuals based on misstatements that post-date registration statements).

C. Lead Plaintiffs' Failure To Plead A Primary Securities Act Violation Requires Dismissal Of The Section 15 Claim.

The Section 15 claim "is derivative of the Section 11 [and Section 12] claim because Section 15 claims require an underlying primary violation of the securities laws." *The Hemmer Grp. v. Sw. Water Co.*, 2016 WL 4488062, at *2 (9th Cir. Aug. 26, 2016). Because Lead Plaintiffs fail to allege sufficiently a Section 11 or Section 12 claim, their Section 15 claim must be dismissed. *See Fresno Cty.*, 607 F. App'x at 696 (upholding dismissal of Section 15 claim "due to [plaintiff's] failure to state a claim for a primary violation of the securities laws").

CONCLUSION

Lead Plaintiffs fail to plead particularized facts supporting their hindsight fraud allegations. Nor do they identify an actionable misstatement or omission in CTI's shelf-registration statement. CTI and the Section 11 Individual Defendants therefore respectfully request that this Court dismiss the claims against them in their entirety.

Bauer. Bauer, a former CTI outside director who signed the shelf-registration statement (*see* Godesky Decl. Ex. 9 at p. II-4), resigned from the Board of Directors on October 20, 2015 (*see* Godesky Decl. Ex. 17), *before* CTI issued the prospectus supplements on which Lead Plaintiffs' claim is based.

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CERTIFICATE OF SERVICE

I hereby certify that on January 9, 2017, I caused the foregoing paper to be electronically filed with the Clerk of the Court using the ECF system which will send notification of such filing to the email addresses denoted on the Electronic Mail Notice List.

/s/ Brendan T. Mangan
Brendan T. Mangan, WSBA #17231

APPENDIX A

Alleged Misrepresentation	Date	Specific Allegation	CAC Citation
Pacritinib's Phase III safety profile was consistent with or better than pacritinib's Phase II safety profile.	March 9, 2015	Press Release stated that "the safety profile in the PERSIST-1 trial was consistent with prior Phase 2 trials" and "the incidence of grade 3 events was lower than observed in Phase 2 trials."	CAC ¶ 140
	March 9, 2015	Call during which Bianco allegedly stated that "the safety profile in PERSIST-1 was consistent with or actually better than what we saw in the published Phase II trials that we presented at ASH in 2013."	CAC ¶ 141
	March 9, 2015	Call during which Bianco allegedly stated that "we don't think [the data is consistent with Phase 2] anymore. We know that it is."	CAC ¶ 142
	March 12, 2015	Form 10-K stated that PERSIST-1 was "consistent with prior Phase 2 trials" and "the incidence of grade 3 events was lower than observed in Phase 2 trials."	CAC ¶ 144
	May 6, 2015	Press Release stated that "the safety profile of pacritinib was generally consistent with previous Phase 2 studies"	CAC ¶ 147
	August 6, 2015	Call during which Bianco allegedly stated that "there were no Grade 4 GI events. And the incidents of Grade 1 to 3 were lower than what we saw in our Phase II studies."	CAC ¶ 153
	September 29, 2015	Call during which Bianco allegedly stated the "side effect profile [in PERSIST-1] was actually better than what we had seen in Phase 2."	CAC ¶ 157
There was limited Phase III discontinuation of pacritinib based on gastrointestinal side effects.	March 9, 2015	Press Release stated that "no grade 4 gastrointestinal adverse events were reported and "very few"—only "three patients"—"discontinued therapy."	CAC ¶ 140
	March 9, 2015	Call during which Bianco allegedly stated that "only three patients discontinued therapy."	CAC ¶ 141

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Alleged Misrepresentation	Date	Specific Allegation	CAC Citation
	March 12, 2015	Form 10-K stated that "very few patients discontinued treatment while on pacritinib or required a dose reduction."	CAC ¶ 144
	May 30, 2015	Press Release stated that "the most common adverse events" were mild to moderate diarrhea, nausea, anemia, thrombocytopenia, and vomiting, "3 patients discontinued therapy," and "gastrointestinal symptoms typically lasted for approximately one week and few patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported."	CAC ¶ 151
	June 12, 2015	Press Release stated that "of the patients treated with pacritinib," only "3 discontinued therapy."	CAC ¶ 152
	August 6, 2015	Press Release stated that only a "limited number of patients discontinued treatment due to side effects."	CAC ¶ 153
	August 6, 2015	Form 10-Q stated that "gastrointestinal symptoms were the most common adverse events and typically lasted for approximately one week. A limited number of patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported."	CAC ¶ 153
	August 6, 2015	Call during which Bianco allegedly stated that "the most common adverse event occurring with pacritinib within 24 weeks of any grade were mild to moderate GI symptoms - were the most common adverse event, and typically last for approximately a week. And only a handful of patients discontinued therapy due to a GI side effect. Importantly, there were no Grade 4 GI events."	CAC ¶ 153
	October 27, 2015	Prospectus Supplement stated that "a limited number of patients discontinued treatment due to side effects" and "there were no Grade 4 gastrointestinal events reported."	CAC ¶ 158

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Alleged Misrepresentation	Date	Specific Allegation	CAC Citation
	November 5, 2015	Form 10-Q stated that "gastrointestinal symptoms were the most common adverse events and typically lasted for approximately one week. A limited number of patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported."	CAC ¶ 160
	December 4, 2015	Prospectus Supplement stated that "a limited number of patients discontinued treatment due to side effects" and "there were no Grade 4 gastrointestinal events reported."	CAC ¶ 165
Pacritinib controls disease-related symptoms better than the alternative therapy.	October 27, 2015 December 4, 2015	Prospectus Supplements stated that "compared to best available therapy . . . pacritinib therapy resulted in a significantly higher proportion of patients with . . . control of disease-related symptoms."	CAC ¶¶ 158, 165
	November 5, 2015	Form 10-Q stated that "[a]dditionally, in June 2015, results from PERSIST-1 patient-reported outcome (PRO) and other quality of life measures presented at a late-breaking oral session at the 20th Congress of the European Hematology Association showed significant improvements in symptom score with pacritinib therapy compared to best available therapy (exclusive of a JAK inhibitor) across the symptoms reported in the presentation."	CAC ¶ 161
The IDMC recommended that BAT patients should not crossover to pacritinib after 24 weeks on the BAT because of non-statistically significant safety concerns.	September 23, 2015 October 27, 2015 November 5, 2015	Prospectus Supplements, press release, and Form 10-Q stated that "The Independent Data Monitoring Committee, or IDMC, for the PERSIST program recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival."	CAC ¶¶ 156, 159, 162
CTI disclosed the "most important" top-line PERSIST-1 data	March 12, 2015	Call during which Bianco allegedly stated that CTI "share[d] the most important information in the [March 9, 2015] top-line release relevant to pacritinib."	CAC ¶ 143

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APPENDIX B

Alleged Misrepresentations

Allegation Underlying Section 10(b) Claim	Allegation Underlying Section 11 and 12(a) Claims
Pacritinib's Phase III safety profile was consistent with or better than pacritinib's Phase II safety profile. *See* Appendix A.	• The March 23, 2015 Form 10-K stated that PERSIST-1 safety results were "consistent with prior Phase 2 trials" and "the incidence of grade 3 events was lower than observed in Phase 2 trials." CAC ¶ 66.
There was limited Phase III discontinuation of pacritinib based on gastrointestinal side effects. *See* Appendix A.	• The March 23, 2015 Form 10-K stated that "very few patients discontinued treatment while on pacritinib or required a dose reduction." CAC ¶ 66. • The August 6, 2015 Form 10-Q stated that "a limited number of patients discontinued treatment due to side effects" and "there were no Grade 4 gastrointestinal events reported." CAC ¶ 67. • The October 2015 Prospectus Supplement stated that "a limited number of patients discontinued treatment due to side effects" and there were no Grade 4 gastrointestinal events reported." CAC ¶ 63. • The November 5, 2015 Form 10-Q stated that "a limited number of patients discontinued treatment due to side effects" and "there were no Grade 4 gastrointestinal events reported." CAC ¶ 74. • The December 2015 Prospectus Supplement stated that "a limited number of patients discontinued treatment due to side effects" and "there were no Grade 4 gastrointestinal events reported." CAC ¶ 71.

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Allegation Underlying Section 10(b) Claim	Allegation Underlying Section 11 and 12(a) Claims
The IDMC recommended that BAT patients should not crossover to pacritinib after 24 weeks on the BAT because of non-statistically significant safety concerns. *See* Appendix A.	• The October 2015 Prospectus Supplement stated that "the Independent Data Monitoring Committee, or IDMC, for the PERSIST program recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival." CAC ¶ 64. • The November 5, 215 Form 10-Q stated that "[t]he Independent Data Monitoring Committee, or IDMC, for the PERSIST program recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival." CAC ¶ 75

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APPENDIX C

Alleged Omissions

Allegation Underlying Section 10(b) Claim	Allegation Underlying Section 11 and 12(a) Claims
CTI and Bianco concealed that "there was an imbalance in the rates of death and serious cardiac events between the two study arms of the PERSIST-1 trial, with nearly twice the percentage of patients treated within pacritinib deceased within the first 24 weeks of the study, and almost the same imbalance of severe cardiac events." *See, e.g.*, CAC ¶¶ 146, 149, 155, 164, 166, 168.	The offering documents concealed that "there was an imbalance in the rates of death and serious cardiac events between the two study arms of the PERSIST-1 trial, with nearly twice the percentage of patients treated within pacritinib deceased within the first 24 weeks of the study, and almost the same imbalance of severe cardiac events." *See, e.g.*, CAC ¶¶ 69, 77.
CTI and Bianco concealed that "the IDMC recommended that CTI terminate the PERSIST-1 study and stop enrollment in PERSIST-2 due to concerns about patient deaths on pacritinib." *See, e.g.*, CAC ¶¶ 146, 149, 155, 164, 168.	The offering documents concealed that "the IDMC recommended that CTI terminate the PERSIST-1 study and stop enrollment in PERSIST-2 due to concerns about patient deaths on pacritinib." *See, e.g.*, CAC ¶¶ 69, 77.
CTI and Bianco concealed that "CTI did not follow the IDMC's recommendation to stop the studies, but instead decided to discharge the IDMC due to supposed concerns about the impartiality of the original IDMC." *See, e.g.*, CAC ¶¶ 146, 149, 155, 164, 168.	The offering documents concealed that "CTI did not follow the IDMC's recommendation to stop the studies, but instead decided to discharge the IDMC due to supposed concerns about the impartiality of the original IDMC." *See, e.g.*, CAC ¶¶ 69, 77.

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